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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-495]

Schedules of Controlled Substances: Extension of Temporary Placement of *N*-Ethylhexedrone, *alpha*-Pyrrolidinohexanophenone, 4-Methyl-*alpha*-ethylaminopentiophenone, 4′-Methyl-*alpha*-pyrrolidinohexiophenone, *alpha*-Pyrrolidinoheptaphenone, and 4′-Chloro-*alpha*-pyrrolidinovalerophenone in Schedule I of the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary rule; temporary scheduling order; extension.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this order to extend the temporary schedule I status of six synthetic cathinones, as identified in this order. The schedule I status of these six substances currently is in effect until July 18, 2021. This temporary order extends the temporary scheduling of these six substances for one year, or until the permanent scheduling action for these substances is completed, whichever occurs first.

DATES: This order, which extends the temporary scheduling order that DEA previously issued for these substances (84 FR 34291, July 18, 2019), is effective July 18, 2021 and expires on July 18, 2022. If DEA publishes a final rule making this scheduling action permanent, this order will expire on the effective date of that rule, if the effective date is earlier than July 18, 2022.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Ph.D., Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362-3249.

SUPPLEMENTARY INFORMATION:

In this order, the Drug Enforcement Administration (DEA) extends the temporary scheduling of the following six controlled substances in schedule I of the Controlled Substances Act (CSA), including their optical, positional, and geometric isomers, salts, and salts of isomers:

- *N*-ethylhexedrone (other name: 2-(ethylamino)-1-phenylhexan-1-one),
- *alpha*-pyrrolidinohexanophenone (other names: α-PHP, *alpha*-pyrrolidinohexiophenone, 1-phenyl-2-(pyrrolidin-1-yl)hexan-1-one),
- 4-methyl-*alpha*-ethylaminopentiophenone (other names: 4-MEAP, 2-(ethylamino)-1-(4-methylphenyl)pentan-1-one),
- 4'-methyl-*alpha*-pyrrolidinohexiophenone (other names: MPHP, 4′-methyl-*alpha*-pyrrolidinohexanophenone; 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)hexan-1-one),
- *alpha*-pyrrolidinoheptaphenone (other names: PV8, 1-phenyl-2-(pyrrolidin-1-yl)heptan-1-one), and
- 4′-chloro-*alpha*-pyrrolidinovalerophenone (other names: 4-chloro-α-PVP, 4′-chloro-*alpha*-pyrrolidinopentiophenone, 1-(4-chlorophenyl)-2-(pyrrolidin-1-yl)pentan-1-one).

Background and Legal Authority

On July 18, 2019, the Acting Administrator of DEA (Acting Administrator) published a temporary scheduling order in the *Federal Register* (84 FR 34291) placing *N*-ethylhexedrone (other name: 2-(ethylamino)-1-phenylhexan-1-one); *alpha*-pyrrolidinohexanophenone (other names: α-PHP, *alpha*-pyrrolidinohexiophenone, 1-phenyl-2-(pyrrolidin-1-yl)hexan-1-one); 4-methyl-*alpha*-ethylaminopentiophenone (other names: 4-MEAP, 2-(ethylamino)-1-(4-methylphenyl)pentan-1-one); 4'-methyl-*alpha*-pyrrolidinohexiophenone (other names: MPHP, 4′-methyl-*alpha*-

pyrrolidinohexanophenone; 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)hexan-1-one); *alpha*-pyrrolidinoheptaphenone (other names: PV8, 1-phenyl-2-(pyrrolidin-1-yl)heptan-1-one); and 4'-chloro-*alpha*-pyrrolidinovalerophenone (other names: 4-chloro-α-PVP, 4′-chloro-*alpha*-pyrrolidinopentiophenone, 1-(4-chlorophenyl)-2-(pyrrolidin-1-yl)pentan-1-one), synthetic cathinones, in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h).[1] That order was effective on the date of publication, and was based on findings by the Acting Administrator that the temporary scheduling of these substances was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Subsection (h)(2) provides that the temporary control of these substances expires two years from the effective date of the temporary scheduling order, i.e., on July 18, 2021. 21 U.S.C. 811(h)(2). However, this same subsection also provides that, during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect to the substance, the temporary scheduling of that substance can be extended for up to one year. Proceedings for the scheduling of a substance under 21 U.S.C. 811(a) may be initiated by the Attorney General (delegated to the Administrator of DEA (Administrator) pursuant to 28 CFR 0.100) on his own motion, at the request of the Secretary of Health and Human Services (HHS),[2] or on the petition of any interested party.

The Administrator, on her own motion, has initiated proceedings under 21 U.S.C. 811(a)(1) to permanently schedule *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP. DEA is simultaneously publishing a notice of proposed rulemaking for the permanent placement of *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP in schedule I elsewhere in this issue of the *Federal Register*. If that

[1] Though DEA has used the term "final order" with respect to temporary scheduling orders in the past, this notice adheres to the statutory language of 21 U.S.C. 811(h), which refers to a "temporary scheduling order." No substantive change is intended.

[2] The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations.

proposed rule is finalized, DEA will publish a final rule in the *Federal Register* to make permanent the schedule I status of these substances.

Pursuant to 21 U.S.C. 811(h)(2), the Administrator orders that the temporary scheduling of *N*-ethylhexedrone, *alpha*-pyrrolidinohexanophenone, 4-methyl-*alpha*-ethylaminopentiophenone, 4'-methyl-*alpha*-pyrrolidinohexiophenone, *alpha*-pyrrolidinoheptaphenone, and 4'-chloro-*alpha*-pyrrolidinovalerophenone, and their optical, positional, and geometric isomers, salts, and salts of isomers, be extended for one year, or until the permanent scheduling proceeding is completed, whichever occurs first.

Regulatory Matters

The CSA provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. Under 21 U.S.C. 811(h), the Administrator, as delegated by the Attorney General, may, by order, place a substance in schedule I on a temporary basis. This same subsection provides that the temporary scheduling of a substance shall expire at the end of two years from the date of the issuance of the order scheduling such substance, except that the Administrator may, during the pendency of proceedings under 21 U.S.C. 811(a)(1) to permanently schedule the substance, extend the temporary scheduling for up to one year.

To the extent that section 811(h) directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued and extended, DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this extension of the temporary scheduling order. The specific language chosen by Congress indicates an intention for DEA to proceed through the issuance of an order instead of proceeding by rulemaking. Given that Congress specifically requires the Attorney General to follow rulemaking procedures for other kinds of scheduling actions, see 21 U.S.C. 811(a), it is noteworthy that, in subsection 811(h), Congress authorized the issuance of temporary

scheduling actions by order rather than by rule. In the alternative, even assuming that this action might be subject to section 553 of the APA, the Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for extending the temporary scheduling order would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety that these substances would present if scheduling expired, for the reasons expressed in the temporary scheduling order (84 FR 34291, July 18, 2019). Further, DEA believes that this order extending the temporary scheduling action is not a "rule" as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act. The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order (E.O.) 12866 (Regulatory Planning and Review), section 3(f), and the principles reaffirmed in E.O. 13563 (Improving Regulation and Regulatory Review). Accordingly, this action has not been reviewed by the Office of Management and Budget.

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 13132 (Federalism), it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

As noted above, this action is an order, not a rule. Accordingly, the Congressional Review Act (CRA)[3] is inapplicable, as it applies only to rules. 5 U.S.C.

[3] This is the colloquial name for Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996.

801, 804(3). It is in the public interest to maintain the temporary placement of *N*-ethylhexedrone, α-PHP, 4-MEAP, MPHP, PV8, and 4-chloro-α-PVP in schedule I because they pose a public health risk, for the reasons expressed in the temporary scheduling order (84 FR 34291, July 18, 2019). The temporary scheduling action was taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. Under 21 U.S.C. 811(h), temporary scheduling orders are not subject to notice and comment rulemaking procedures. DEA understands that the CSA frames temporary scheduling actions as orders rather than rules to ensure that the process moves swiftly, and this extension of the temporary scheduling order continues to serve that purpose. For the same reasons that underlie 21 U.S.C. 811(h), that is, the need to place these substances in schedule I because they pose an imminent hazard to public safety, it would be contrary to the public interest to delay implementation of this extension of the temporary scheduling order. Therefore, in accordance with section 808(2) of the CRA, this order extending the temporary scheduling order shall take effect immediately upon its publication. DEA will submit a copy of this extension of the temporary scheduling order to both Houses of Congress and to the Comptroller General, although such filing is not required under the CRA, 5 U.S.C. 801–808, because, as noted above, this action is an order, not a rule.

Anne Milgram,
Administrator.
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